MAY 2 3 2000

K000760

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTACT PERSON: Michelle L. McKinley

DEVICE NAME: Reach Femoral Component

CLASSIFICATION NAME: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (888.3358) and hip joint metal/ceramic/polymer semi-constrained porous coated cemented prosthesis (888.3350)

INTENDED USE:

The Reach Femoral component is indicated for use in reconstruction of the hip joint due to:

a.) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previous failed total hip arthroplasty.

The Reach Femoral Component is intended for press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. This device is a single use implant.

DEVICE DESCRIPTION:

The device is composed of a metallic femoral stem, which is designed to articulate with a commercially available Biomet acetabular component.

The trunion of the Reach femoral component is a Biomet Taper Type I and is compatible with all Taper Type I modular heads. The Reach femoral component geometry is designed for proximal, as well as, distal stability and gradual offloading into the bone along the canal. The proximal 100 mm of each stem incorporates a bi-planar taper to encourage proximal offloading, thus reducing stress shielding. This broad proximal geometry fills a greater portion of the metaphysis, which aids in rotational stability. The Reach femoral component is available in two lengths, 200 mm and 250 mm, and five diameters: 11 mm, 13mm, 15 mm, 17 mm, and 19 mm. The 200 mm Reach femoral component is available as an universal or anatomical component, which would allow the

surgeon to reconstruct the dimensions of the natural femur. The 250 mm femoral stem is available as an anatomical component only.

The stem has a porous coated duckbill collar, which is incorporated to provide component stability and stress transfer. The underside of the collar is porous coated to help ensure collar-calcar contact and stress distribution.

A bolt hole through the proximal lateral aspect of the component gives the surgeon the option of using the Mallory Head Claw or Reach Trochanter Anchor Washer and a Trochanter Bolt. This assembly will allow the greater trochanter to be compressed against the prosthesis for enhanced fixation and proximal stability. This design will also provide a method for reattaching the greater trochanter in cases where a trochanter osteotomy has been performed.

The Mallory Head Claw and the Reach Anchor Washer are additional fixation components, which provide supplemental fixation when there has been a trochanteric osteotomy or poor bone stock. The devices were designed to increase the area of contact of the implant on the greater trochanter, which should reduce the contact stress. The claw is manufactured from cast cobalt alloy and spans a larger distance superior to inferior with pointed fingers at the corners to affix into and over the top of the greater trochanter. The Reach Anchor Washer is manufactured from titanium alloy .

Distally, the stem is cylindrical after 100 mm with an anterior bow for left and right specific applications. The distal anterior bow more closely matches the anatomic femur to provide rotational stability. This cylindrical design will also enhance implant stability by providing a potential area of biological fixation in situations of proximal bone deficiencies.

The Reach Femoral Components are fully porous coated to provide maximum proximal and distal fixation through tissue ingrowth. This circumferential closed-pore coating potentially seals the femur from debris migration. Porous coating on the underside of the collar along with extended proximal to distal porous coating, provide areas of potential tissue ingrowth in crucial regions of cortical bone. The distal tip of the stem has a polished finish, to prevent distal offloading and fixation of the tip.

POTENTIAL RISKS:

The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Bone fracture
Cardiovascular disorders	Hematoma
Implant loosening/migration	Blood vessel damage
Soft tissue imbalance	Nerve damage
Deformity of the joint	Excessive wear
Tissue growth failure	Infection

Delayed wound healing	Dislocation
Metal sensitivity	Breakdown of the porous surface

SUBSTANTIAL EQUIVALENCE:

The Reach Femoral Component is similar to previously marketed devices. Direct comparison was made with the following predicates:

Reach Femoral Component
Mallory Head Modular Calcar Replacement Components

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K000760
Trade Name: Reach Femoral Component
Regulatory Class: II
Product Code: LPH
Dated: March 6, 2000
Received: March 8, 2000

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000760

DEVICE NAME: Reach Femoral Stem

INDICATIONS FOR USE:

The Reach Femoral Stem is indicated for use in reconstruction of the hip joint due to:

a.) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previous failed total hip arthroplasty.

The Reach Femoral Stem is intended for press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 21 CFR 801.109 (Per 21 CFR 801.109) OR Over-The-Counter Use No (Optional Format 1-2-96)

Dianne R. Vachon
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000760